

# **Exhibit 5**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION**

MEDLINE INDUSTRIES, INC.	)	
	)	
Plaintiff,	)	No. 14-cv-3618
	)	
vs.	)	Judge John Z. Lee
	)	
C.R. BARD, INC.	)	
	)	
Defendant.	)	

**EXPERT REPORT OF DR. EDWARD YUN  
RELATED TO DAMAGES, NON-INFRINGEMENT, AND NEW  
EVIDENCE OF ALLEGED SECONDARY CONSIDERATIONS**

**(CONTAINS INFORMATION THAT MEDLINE HAS DESIGNATED AS  
CONFIDENTIAL AND HIGHLY CONFIDENTIAL)**

described in my reports both from the perspective of the person of ordinary skill in the art as defined by Ms. Weintraub and from the perspective of a urologist.

Regardless, I reach the same opinions here as well as in my original report.

13. I also understand that establishing infringement of a method claim requires that Medline show that the claimed steps are actually being performed by Bard's customers, not hypothetically performed. The concept of a person of ordinary skill in the art as applied to whether the claimed method steps are actually performed by Bard's customers is not particularly helpful because in real-world hospital settings catheterizations are most often performed by persons with more than ordinary skill (e.g., a urologist with ten years of experience) as well as less than ordinary skill (e.g., a nurse inserting his or her first catheter). The number of catheterizations performed by nurses with the precise level of experience as defined by Ms. Weintraub to be of ordinary skill is likely quite low.

## **VI. EXPERIENCE WITH BARD AND MEDLINE CATHETER KITS**

14. I have admitting privileges at seven hospitals: Riverside Community Hospital, Parkview Community Hospital, Loma Linda University Medical Center Murrieta, Corona Regional Medical Center, Inland Valley Medical Center, Rancho Springs Medical Center, and Temecula Valley Hospital. These hospitals use a variety of Foley catheter kits so I have experience using various kits sold by both Medline and Bard. In particular, I have experience using (and also currently use)

the Bard SureStep tray products (both the version with the opening in the divider wall and newer version), the Medline ERASE CAUTI tray products, and the Bard Advance tray products. In the past, I have also used the Bardex I.C. catheter tray products, which I understand to also be referred to as the Legacy tray.

15. In my report related to invalidity, I describe the steps that are performed when catheterizing a patient using a Foley catheterization kit in paragraphs 34 through 42. These steps would be performed in the same manner regardless of the tray product that is utilized, i.e., regardless of whether it is a SureStep, ERASE CAUTI, Advance or Legacy tray product. Indeed, in my current practice, I frequently switch back and forth between these trays and have experienced no difference in how a Foley catheterization procedure is performed based on the kit used.

16. Over the years, the brand and types of Foley catheter kit products being used have changed at certain of the seven hospitals where I have admitting privileges. I have general familiarity with these changes and have confirmed which trays were currently and previously used at each hospital by discussing these matters with individuals in the purchasing departments at these hospitals.

17. Riverside Community Hospital has long been a Bard customer and purchases trays directly from Bard. Riverside currently purchases the Bard SureStep tray and has done so since mid-2014 and also purchased Bard Foley

ERASE CAUTI trays because of price discounts or because these products are pushed by Medline sales representatives. In contrast, where Medline does not serve as a distributor, other Foley catheter kit products may be pushed by these distributors such as Bard or Covidien tray products. As explained above, Loma Linda University Medical Center Murrieta is a facility where the Foley catheter kit purchasing decision appears to be largely tied to the distributor utilized by the hospital.

24. A third factor is price. Hospitals may switch to a particular tray as a cost saving measure, for example, as with the UHS hospitals switch to the ERASE CAUTI tray.

25. A fourth factor is the quality of the components inside the tray. For example, the UHS hospitals switch from Medline to Bard products because of quality issues with Medline's Foley catheter.

## **VII. PERFORMANCE OF CLAIM STEPS OF '190 PATENT AND '786 PATENT**

26. I have been asked whether the claim steps recited in the '190 Patent and '786 Patent are necessarily performed using the SureStep tray. I am quite familiar with this tray and how it is used by urologists and nurses given my personal experience and experience training others to perform catheterizations procedures.

**B. '786 Patent**

27. I have been asked whether each claim step of claim 1 of the '786 Patent is necessarily performed using the SureStep tray. In my experience, each step is not always performed with the SureStep tray (or with any Foley catheter tray product). Specifically, the step "placing one of the one or more layers of wrap or the additional layer of wrap beneath a patient, thereby transforming an area beneath the patient from a non-sterile field to a sterile field" is not always performed when performing a Foley catheterization, including with the SureStep tray. I understand that this claim requires that the wrap that is placed beneath a patient is a wrap that is retrieved from the tray. Although patients usually have a wrap, pad, or chuck underneath them when being catheterized, often this wrap does not come from the tray. In that case, this step is not performed.

28. The surface area of the tray-provided wrap is rather small and often does not even cover the entire area of a patient's buttocks, making the wrap ineffective. Hospitals have their own supply of underpads, known as a chuck, which are larger, fit more effectively under a patient, and are more absorbent than the wraps included in the catheter kits. Thus, when I perform Foley catheterizations, I commonly instruct the nurse to place a chuck under the patient rather than use the included underpad. To the extent the underpad is used, in my experience, it is most commonly placed beneath a patient's buttocks and thighs..

29. Another reason that the step of placing a wrap from the tray under the patient is not often performed is the use of catheters in surgery. Surgical patients are commonly catheterized using an indwelling catheter. As I noted in my opening report, I frequently placed Foley catheters in surgical patients as a medical resident because surgeons often requested that a urologist place a catheter. I also often perform surgeries as part of my current practice. Based on my experience catheterizing patients in a variety of surgical procedures, I note that surgical patients are already placed on hospital-supplied pads. Thus, an underpad from the tray will not be placed under a patient when performing a Foley catheterization using a kit such as the SureStep. I have placed hundreds of catheters for surgical patients (both urological and non-urological surgeries) and have never placed a wrap from the kit under the patient or instructed anyone else to do so.

**C. '190 Patent**

30. I have been asked whether each claim step of claims 14-18 of the '190 Patent is necessarily performed using the SureStep tray. I understand that claim 14 of the '190, which is dependent on claim 1, requires performing the following steps:

accessing an instruction manual comprising a health care services portion and a patient portion detachably coupled thereto;

detaching the patient portion from the health care services portion; and

delivering the patient portion to the patient.

31. I understand that claim 16 requires “delivering a patient portion of an instruction manual to a patient.” I understand that claim 17 requires “detaching the patient portion from a health care services portion.”

32. For the reasons noted in my previous report, patient instructions are often not delivered to the patient. Additionally, I understand that these claims require detaching a patient portion from a healthcare services portion. I have never witnessed this being done and am not aware of this ever being done. As patient instructions are often not delivered, requiring an additional step of detaching the patient instructions before delivery would likely only increase the number of patient instructions that end up being disposed in the trash, instead of being delivered to the patient. For this reason, each of the steps of claims 14, 15, and 17 are not necessarily performed when using the SureStep.

33. Claims 14-18 all require the performance of the following step: “passing at least a portion of the catheter assembly from a second compartment of the tray through an opening in a first barrier separating the first compartment from the second compartment, thereby passing the at least the portion of the catheter assembly through the lubricating jelly.” I have been asked whether this step would necessarily be performed using the SureStep tray that included an opening in a divider wall between the first and second compartment. I am not aware of this ever being performed and my opinion is that it would most often not be performed.



34. I discussed the different methods of lubricating a catheter in my original report. Some of these methods foreclose the performance of this step. For example, male patients are often lubricated by directly injecting lubricant into the urethra, in which case the tray is not used to lubricate the catheter. When this technique is utilized, the step of “passing at least a portion of the catheter assembly from a second compartment of the tray through an opening in a first barrier separating the first compartment from the second compartment” would not be performed. But even where the catheter is lubricated within the tray, I disagree that this step would be necessarily (or even often) performed.

35. While the tray itself defines a sterile field, the sterile field extends above the top of the tray. Thus, there is no need to keep the components below the highest portion of the tray wall when manipulating them inside the tray. As such, when lubricating the catheter in the first compartment of the SureStep tray, the catheter can easily be passed over the divider wall between the compartments without removing the catheter from the sterile field. Based on my experience lubricating catheters, this is the most efficient and common method of using the SureStep tray to lubricate the catheter.

36. While it would be technically possible to pass the catheter through the opening to lubricate the catheter when using the previous version of the SureStep tray, it would take longer and be more difficult to do so. The method of passing it

through an opening would also have no clinical benefits as compared to simply passing it over the wall because in either case the catheter remains within the sterile field formed by the tray.

37. Given the above and based on my experience lubricating catheters including when using the SureStep tray, my opinion is that the catheter would most often be lubricated using the SureStep tray by passing it over the wall as opposed to through the opening. I am not personally aware of any instances in which the catheter was lubricated by using the opening, which I am aware was subsequently removed by Bard in an updated version of the tray. Based on my experience using both versions of the tray, I note that the catheter is lubricated with equal ease with the new SureStep tray that excludes the opening, which further suggests that using the opening of the previous tray was not necessary to lubricate the Foley catheter in an efficient and clinically prudent manner. I have never heard any complaints or negative feedback regarding the removal of the opening from the divider wall of the SureStep tray, which further indicates this did not change how the catheter was lubricated in the tray.

#### **VIII. MEDLINE'S ALLEGED EVIDENCE OF A REDUCTION IN CAUTI RATES**

38. I previously considered evidence related to Medline's claim that its ERASE CAUTI tray products reduce CAUTIs rates. As explained in my original report, based on my review of the evidence, this claim is unsupported. I have

continue, which may include reviewing documents and other information that may yet be made available to me. Accordingly, I expressly reserve the right to continue my study in connection with this case and to expand or modify my opinions and conclusions as my study continues.

73. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on Date: \_\_7/23/19\_\_

A handwritten signature in black ink, appearing to read 'Edward Yun', is written above a horizontal line.

Dr. Edward Yun